

Navajo Nation Human Research Review Board Meeting Agenda

Meeting Date: 2024-03-19 Meeting Time: 8:15 AM
Location: Virtual

MEMBERS:

- Dr. Paul Charlton, MD - Medicine
- Dr. Christopher Jentoft, MD - Medicine
- Dr. David Begay, Ph.D. - Scientific Education
- Mr. Delvin Yazzie, MPH - Epidemiology
- Dr. Kalvin White, Ph.D. - Scientific Education
- Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bioethics
- Dr. Paula Mora, MD - Medicine/ Public Health
- Dr. Rebecca Izzo-Manymules, Ph.D. - Chairperson - Education
- Dr. Sonya Shin, MD - Medicine

OLD BUSINESS:

I. Meeting Call to Order:

II. Call for Roll Call:

- Invocation:

- Introductions:

III. Review and Approval of January 16, 2024 Meeting Minutes.

IV. Review and Acceptance of Quarterly reports:

NEW BUSINESS:

V. Review and Acceptance of New Presentations:

VI. Acceptance and Approval of Returning Presentations:

VII. Review and Approval of Manuscripts: 1) Request Review and Approval of Manuscripts to Publish titled: Hozho (Heart Failure Optimization at Home to Improve Outcomes) Improving the Quality of Heart Failure Care through Telephone-Based Guideline-Director Medial Therapy Optimization in Navajo Nation. NNR-23.470 Dr. Lauren Eberly, MD, 2) Haemophilus influenzae type b vaccine immunogenicity in American Indian/Alaska Native infants. NNR-20.374 Dr. Laura Hammitt, MD. 3) A Phase 3 Trial to Evaluate the Safety, Tolerability, and Immunogenicity of V114, a 15-Valent Pneumococcal Conjugate Vaccine, Followed by

23-Valent Pneumococcal Polysaccharide Vaccine 6 Months Later, in adults 18-49 Years of Age (PNEU-DAY): Subgroup Analysis Based on Enrollment at Center for Indigenous Health sites, NNR-18.307 Dr. Laura Hammitt, MD, 4) Trajectory of antibody responses one year following SARS-CoV-2 infection among Indigenous individuals in the Southwest United States, NNR-19.350 Dr. Laura Hammitt, MD VIII. Acceptance and Approval of Serious Adverse Events (SAEs):

IX. . Noon Hour Discussion: 12 Noon to 1 PM: Ms. Kim Russell, Navajo Department of Health Director; Dr. Gregory Germino, MD, Deputy Director National Institute of Diabetes and Digestive and Kidney Disease - NIH; Dr. Karina Walters, Ph.D. Director Tribal Health Research Office NIH.

X. Announcements NNHRRB Worksession 1-4 PM: Revision of Navajo Nation Research Code, Update NNHRRB By-Laws, Revise NNHRRB Policies and Procedures / Adjournment of Meeting:

QUARTERLY REPORTS

1. NNR-11.348 PI: Simental Francisco
Navajo Behavioral Risk Factor Surveillance Survey
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering 1) October 1 - December 31, 2023, 2) July 1 - September 30, 2023 periods

2. NNR-23.471 PI: Delphina Dayish
Navajo Grandparents Raising Their Grandchildren: Their Challenges and Needs
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering January 1, 2024 - March 31, 2024 period

3. NNR-19.349 PI: Tasha Seneca Keyes
Restorative Justice practices for improving school-based relationships
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering December 2023 - March 19, 2024 period

4. NNR-19.367 PI: Craig Chaya
Patterns of Blindness in the Navajo Nation: A Retrospective Study
Reason on Agenda: Quarterly Review
Description: Request Acceptance and Approval of Quarterly Report covering July 1 - December 31, 2023 period

5. NNR-20.389 PI: Olivia Lindly
Parents Taking Action to Improve Autism Services Access for Navajo Families in Northern Arizona:
Intervention Adaptation and Pilot Trial
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering November 1, 2023 - January 31, 2024 period

6. NNR-21.430 PI: Elise Christopher
High School & Beyond Longitudinal Study of 2022 (HS&B:22)
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October 20, 2023 - January 20, 2024 period

7. NNR-23.480 PI: LaNaya Cook
Teacher's Experiences in Motivating and Helping Navajo Students Academically and Developing or Improving
Self-Efficacy: A Qualitative Descriptive Study
Reason on Agenda: Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering November 16, 2023 - February 23, 2024 period

NEW PRESENTATION(S)

1. NNR-23.485 PI: Harrison Cayatineto

microRNA Based Inhibition against the Nucleocapsid Protein Synthesis in Bovine Viral Diarrhea Virus: A Surrogate Model for Hepatitis C. Virus

Reason on Agenda: New Title

Description: Request Review and Approval of New Study - Submission of 1) Din'e Hataalii Resolution, 2) Navajo Historical Preservation Letter, 3) Din'e College IRB Letter, 4) Revise Consent list Dr. Izzo-Manymules as contact, 5) Revise Interview questionnaire TABLED at 8-15-23 PI to submit Din'e Hataalii Resolution, Navajo Historical Preservation Letter, Din'e College IRB Letter, Revise Consent list Dr. Izzo-Manymules as contact, Revise Interview questionnaire. TABLED at 11-21-23 Meeting

2. NNR-24.494 PI: Dana Dabelea

DISCOVERY of Risk Factors for Type 2 Diabetes in Youth Consortium: Navajo-Shiprock Site

Reason on Agenda: NEW

Description: Remarks: Request Acceptance and Approval of New Study- TABLED - February 20, 2024 (Colorado University IRB Letter, NAIHS Letter, Specimen distruction and Data Storage); Date Received - 02/05/2024

3. NNR-24.495 PI: Priscilla Sanderson

Hozhoogoo Naashaa doo (I Will Live in a Good Way): Breast Cancer Prevention

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study - TABLED February 20, 2024 Meeting (University IRB Letter, revise Interview questions, Navajo Historic Preservation Letter); Date Received - 02/07/2024

4. NNR-24.496 PI: Rebecca Bird

Dib'e Wolgh'eii nima at'e: The Din'e Sheep Camp as a socioecological system

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 02/29/2024

5. NNR-24.497 PI: Tammy Yazzie

A Qualitative Study on Din'e Hataali Traditional Native Healing Methds in the Treatment of Alcohol Use Disorder

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 03/08/2024

RETURNING PRESENTATION(S)

1. NNR-16.257 PI: Kevin Lombard

Engaging Family and School in Navajo Gardening for Health

Reason on Agenda: Final Report

Description: Request Acceptance and Approval Final Report covering September 20, 2023 - January 16, 2024 study period. And Request to Close Study. Data Jump drive submitted to Navajo Research Office. TABLED at February 20, 2024 Meeting, PI not available.

2. NNR-19.333 PI: Kevin Lombard

Engaging Navajo Elementary Schools in Randomized Controlled Trial of Y'eego! Healthy Eating & Gardening

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 21, 2024 - February 18, 2025 period TABLED at February 20, 2024 (PI Not Available)

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 16, 2023 -February 20, 2024 period TABLED at February 20, 2024 Meeting (PI Not Available)

3. NNR-21.405T PI: Emily Haroz

Pilot Evaluation of Psychological First Aid for Frontline Workers in American Indian/Alaska Native Communities

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 20, 2024 - April 20, 2025 period

4. NNR-23.470 PI: Lauren Eberly

Improving the Quality of Heart Failure Care for Patients Receiving Care Through the Indian Health Service at the Gallup Service Unit

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 18, 2024 - April 18, 2025 period

5. NNR-18.319 PI: Bryan Jones Brayboy

Culturally Responsive Making: Developing High-Low Tech Maker Activities in Local and Mobile Spaces for Supporting American Indian Youth

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering September 18, 2023 - September 18, 2024 period

Reason on Agenda: Final Report

Description: Request Acceptance and Approval of Final and to Close Study covering September 18, 2022 - September 18, 2023 period

6. NNR-05.175 PI: Kimberly Mohs

Navajo Area Indian Health Services - Cardiovascular Risk Reduction Demonstration Project

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 1, 2023 - December 31, 2023 period
TABLED at February 20, 2024 (PI Not Available)

7. NNR-19.360 PI: Debra MacKenzie

Navajo Birth Cohort Study/environmental Influences on Child Health Outcomes Plus (NBCS/ECHO+)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Modification: 1) Clarification on Consent Form, address for Vanderbilt analysis center and corrected the amount blood drawn. 2) Flashdrive for digital copies of survey added for Cycle 2 and additional supporting documentation. AT JANUARY 16, 2024 to add Protocol Modification. TABLED at February 20, 2024 Meeting (Need more clarification)

8. NNR-22.460 PI: Ashish Amresh

Project Lets Talk Code

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 18, 2023 - April 17, 2024 period

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 18, 2024 - April 17, 2025 period

9. NNR-15.199 PI: Carmen George

REACH for Healthy Navajo Communities.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 17, 2024 - March 17, 2025 period

Reason on Agenda: Change in Investigators

Description: Request Acceptance and Approval of Change of Principal Investigator from Ms. Carmen George to New Principal Investigator Ms. Olivia Muskett, attachments: Part 5 Certification, CV,

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan of Findings to the Community and Partners.

10. NNR-17.293 PI: Jonathan Davis

Evaluating Geodesign as a Planning Framework for Navajo Nation Chapters

Reason on Agenda: Continuation Request

Description: Request Acceptance and approval of Continuation Request covering January 16, 2024 - January 16, 2025

period TABLED at February 20, 2024 Meeting (PI Not Available)

Reason on Agenda: Annual Report

Description: Request Acceptance of Approval of Annual Report covering January 16, 2023 - January 16, 2024 period
TABLED at February 20, 2024 Meeting (PI Not Available)

Reason on Agenda: (Other)

Description: Review and Acknowledge of Photo fo Coppermine Winning in Public Outreach 2022 from Arizona Chapter of the American Planning Association. TABLED at February 20, 2024 (PI Not Available)

11. NNR-16.247 PI: Bruce Bender

Creating an asthma collaboration to reduce childhood asthma disparities on the Navajo Nation

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Conference Presentation titled: "Navigating Asthma Disparities and School-Based Stock Inhaler Program Implementation Challenges on the Navajo Nation" at Annual Meeting of the Midwest Clinical and Translational Science in Chicago, Ill in April 2024.

12. NNR-17.277 PI: Denise Charron-Prochownik

Stopping Gestational Diabetes in Daughters and Mothers - Phase 2

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Conference Presentation titled "Reproductive Health (RH) and gestational diabetes (GDM) Knowledge mediates the intervention effect on self-efficacy for pregnancy planning in dyads of American Indian and Alaska Native(AIAN) female adolescents and young adults (FAYA) at risk for GDM and their adult female caregivers" at International Society of Pediatric and Adolescent Diabetes (SPAD) 2024 Scientific Conference at Lisbon Portugal, on October 16-19, 2024

13. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 22, 2023 - January 21, 2024 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 22, 2023 - January 21, 2024 period

14. NNR-19.331 PI: Cathron Donaldson

Understanding Navajo Parents' Beliefs about Cradling and Early Mobility Practices

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 19, 2024 - February 19, 2024 period

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 19, 2023 - February 19, 2024 period

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Plan of Qualitative Data.

15. NNR-21.397 PI: Manley Begay, Jr.

Understanding Resilience and Mental Wellbeing: Southwest Indigenous Nations and the Impact of COVID-19

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Oral Presentation Conference Presentation titled: COVID-19 Pandemic, Mental Well-being and Resilience: Voices from Three Indigenous Nations in the Southwest. at American Public Health Conference on October 27-30.

16. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Abstract for Conference Presentation titled: "The Feasibility of Controlled Environment Agriculture from the Perspectives of Indigenous Farmers in the Four Corners" and Presentation Titled: "Preliminary Navajo Nation Water Survey Results" at New Mexico Water Workshop in Albuquerque, NM on April 4-5, 2024.

17. NNR-22.447 PI: Amanda Fretts

Development and Evaluation of a Culturally-informed Food Insecurity Screening Protocol with American Indian Adults from Northern Navajo Medical Center

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 25, 2023 - February 23, 2024 period

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Conference Presentation titled: Development and evaluation of a culturally-informed food insecurity screening protocol with American Indian Adults: Evidence from Northern Navajo Medical Center. at 23rd meeting of International Society of Behavioral Nutrition and Physical Activity on May 20-23, 2024 at Omaha, NE

18. NNR-23.477 PI: Mayela Gillan

Understanding Workplace Hazards while Remediating Legacy Uranium Mine Waste in Cove Chapter

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 15, 2023 - February 15, 2024 period

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add two undergraduate research assistants to the

Protocol. 1) Diana Giron 2) Giana Joann Median. attached University of California Berkeley Protection of Human Subjects Letter, Part 5 Certification, CV.

19. NNR-22.449 PI: Ashley Thacker

Dine' Household Water Survey

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for Conference Presentation at U.S. Indigenous Data Sovereignty and Governance Summit on April 11-12 in Tucson, AZ

20. NNR-23.492 PI: Kristin Mitchell

NATIVE-RISE (Risk Identification for Suicide and Enhanced Care)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add Pre-Trial Observation Phase, that will inform the subsequent Randomized Controlled Trial (RCT) of the Research Plan.

21. NNR-22.449 PI: Ashley Thacker

Dine' Household Water Survey

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Three Amendments: 1) Expand Implementation of this project into the remaining 4 agencies of Navajo Nation of Phase 2; 2) Addition of follow-up for participants whose water samples test positive for e.coli; 3) Updates to the water questionnaire and water sample collection form.

22. NNR-22.457 PI: Joshua Allison-Burbank

Language is Medicine: A Language Nutrition Intervention to Prevent Development Delay in Dine Children

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Two Amendments: 1) Addition of procedures for study participants who are lost to follow-up, 2) Introduction of personnel Jessica Meese, MS, CCC-SLP as Project Coordinator

23. NNR-19.367 PI: Craig Chaya

Patterns of Blindness in the Navajo Nation: A Retrospective Study

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering January 21, 2023 - January 21, 2024 period

SERIOUS ADVERSE EVENT

1. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Hip Replacement

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID-19

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID-19

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Sepsis

Last Page and End of Agenda